

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ASTELLAS US LLC; ASTELLAS
PHARMA US, INC.; and GILEAD
SCIENCES, INC.,

Plaintiffs,

v.

APOTEX INC. et al.,

Defendants.

C.A. No. 18-1675-CFC

(CONSOLIDATED)



**PLAINTIFFS' LETTER BRIEF REGARDING PLAINTIFFS' MOTION
TO COMPEL DRL TO PRODUCE A PREPARED CORPORATE DESIGNEE**

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[REDACTED]

Dear Judge Burke:

Plaintiffs Astellas US LLC; Astellas Pharma US, Inc.; and Gilead Sciences, Inc. (collectively, “Plaintiffs”) respectfully request that the Court order Defendants Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “DRL”) to produce a 30(b)(6) designee who is adequately prepared to testify regarding Plaintiffs’ 30(b)(6) Topics 4, 8, 9, 12, 13, and 38.¹

The patents-in-suit are directed to regadenoson monohydrate and related compositions and methods. The patents describe and exemplify several different forms or “polymorphs” of regadenoson, including “Form A,” which “has been shown to be a monohydrate.” *E.g.*, Ex. A at 6:54-67 (U.S. Patent No. RE47,301). Plaintiffs assert that DRL directly and indirectly infringes the patents-in-suit. Whether the API used to make DRL’s ANDA product contains regadenoson “monohydrate” and whether DRL had knowledge of that fact are key disputes. [REDACTED]

[REDACTED], X-ray diffraction (“XRD” or “XRPD”) testing can be used to identify the material contained in DRL’s API.

Federal Rule of Civil Procedure 30(b)(6) requires a corporation to “prepare its designee ... to give binding answers on its behalf ... [and] perform a reasonable inquiry for information that is noticed and reasonably available to it.” *Oy v. Verizon Servs. Corp.*, No. 12-cv-00715-CJB, 2013 WL 5675516, at *2 (D. Del. Oct. 15, 2013) (Burke, M.J.) (internal quotation omitted). The “duty of preparation goes beyond matters personally known to the designee ..., and if necessary the deponent must use documents, past employees or other resources to obtain responsive information.” *Id.* (internal quotation omitted). “[P]roducing an unprepared [Rule 30(b)(6)] witness is tantamount to a failure to appear that is sanctionable under Rule 37(d).” *Black Horse Lane Ass’n, L.P. v. Dow Chem. Corp.*, 228 F.3d 275, 304 (3d Cir. 2000) (internal quotation omitted).

On April 6, 2020, Plaintiffs noticed a deposition of DRL pursuant to Rule 30(b)(6). Among other things, Plaintiffs sought testimony on two categories of topics: (1) testing or analyses of DRL’s API, including XRPD testing to assess the form of the API (Topics 4, 8, 9, 12, and 13); and (2) certain communications between DRL and Euticals Inc. (“Euticals”), the company that manufactures regadenoson API for DRL (Topic 38). Ex. C at A-4 to A-6, A-9 (30(b)(6) Deposition Notice). DRL designated Dr. Sumitra Ashok Pillai to testify on these topics. Ex. D at 10-11, 16-17, 20-22, 48-49 (Second Am. Response to 30(b)(6) Deposition Notice). However, Dr. Pillai was wholly unprepared to do so, in violation of DRL’s obligations under Rule 30(b)(6).

I. Dr. Pillai Was Unprepared To Testify About Testing And Analyses Of DRL’s API Conducted By DRL Or On Its Behalf.

DRL produced documents showing that [REDACTED]

[REDACTED]

¹ In an effort to narrow the dispute, Plaintiffs no longer seek testimony regarding Topic No. 10.

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[REDACTED] Although this XRPD testing falls squarely within Topics 4, 8, 9, 12, and 13, [REDACTED]

[REDACTED] DRL failed to fulfill its duty to prepare Dr. Pillai regarding DRL's knowledge of [REDACTED] because DRL never arranged conversations between Dr. Pillai and the DRL employees who [REDACTED]

[REDACTED] See *Nacco Materials Handling Grp., Inc. v. Lilly Co.*, 278 F.R.D. 395, 401 (W.D. Tenn. 2011) (allowing corporate witness to be re-deposed where witness failed to speak to employees with relevant information to prepare for deposition).

Dr. Pillai was similarly unprepared to address [REDACTED]

DRL's refusal to prepare Dr. Pillai to testify beyond the face of documents concerning XRPD analyses [REDACTED] is improper. Ex. J at 231:5-7 (Pillai Dep.) (DRL's counsel claiming Dr. Pillai "can only direct you to what is disclosed in the documents"). Preparing a 30(b)(6) witness to provide a "rote response" is insufficient. *Scott Hutchinson Enters., Inc. v. Cranberry Pipeline Corp.*, 318 F.R.D. 44, 55 (S.D. W. Va. 2016); see also Ex. L, *Guardant Health*,

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Inc. v. Personal Genome Diagnostics, Inc., No. 1:17-cv-01623, D.I. 262 (D. Del. May 21, 2019) (allowing additional deposition time of corporate witness when “[t]he substance of [the witness’s] repeated answer was simply not aligned with the substance of the questions” and was “essentially ... a non-response” (internal citation omitted)); *Oy*, 2013 WL 5675516, at *3 n.3 (designee must be prepared beyond providing “verbatim recitation” of documents). DRL [REDACTED] regadenoson XRPD testing, and Plaintiffs are entitled to delve into DRL’s knowledge about [REDACTED] beyond what appears on the face of DRL’s documents.

Nor can DRL avoid its obligation to prepare its Rule 30(b)(6) designee on the ground that Dr. Pillai herself is not knowledgeable about XRPD analyses. If technical topics concern “highly relevant information,” selecting as a designee someone “who lack[s] knowledge about many of the technical topics ... is plainly egregious.” *Meyer Corp. U.S. v. Alfay Designs, Inc.*, No. CV 2010 3647 CBA MDG, 2012 WL 3536987, at *9 (E.D.N.Y. Aug. 13, 2012). *Oy*, 2013 WL 5675516, is instructive. There, the corporate designee testified that he “d[id] not have a ‘technical background’ and did not ‘understand ... technical stuff.’” *Id.* at *3. The Court found the witness “failed to provide substantive answers to even the most basic questions” for certain topics and concluded that he was an “inadequate Rule 30(b)(6) witness.” *Id.* at *3-4. Dr. Pillai similarly asserted that she [REDACTED]

[REDACTED] Ex. J at 109:19-24, 116:8-13 (Pillai Dep.). But DRL’s own employees regularly [REDACTED] Dr. Pillai was obligated to educate herself on information within DRL’s knowledge, and DRL cannot feign ignorance by refusing to prepare a witness to testify about these technical topics.

II. Dr. Pillai Was Unprepared to Testify About DRL’s Communications With Euticals.

Dr. Pillai also failed to prepare to testify on behalf of DRL for Topic 38 because she did not speak with anyone about communications between Euticals and DRL regarding DRL’s regadenoson API in preparation for her deposition. *Id.* at 15:6-10, 29:16-33:16, 178:3-18. [REDACTED]

[REDACTED] Dr. Pillai’s failure to investigate DRL’s communications with Euticals regarding regadenoson API and XRPD testing is improper. *Pioneer Drive, LLC v. Nissan Diesel Am., Inc.*, 262 F.R.D. 552, 559 (D. Mont. 2009) (“Defendant failed its obligation ... under 30(b)(6)” when deponent “did not enquire about the history or production of the documents” beyond brief discussion).

* * *

Dr. Pillai did “[b]asically nothing” to prepare for Plaintiffs’ topics concerning XRPD testing and communications with Euticals about the same. *See CMI Roadbuilding, Inc. v. Iowa Parts, Inc.*, 322 F.R.D. 350, 361 (N.D. Iowa 2017). Plaintiffs respectfully request that the Court compel DRL to produce a prepared witness to testify regarding Topic Nos. 4, 8, 9, 12, 13, and 38.

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Respectfully submitted,

/s/ Robert M. Oakes

Robert M. Oakes

cc: Counsel of Record for DRL